

Application No. 10/088,966

Reply to Office Action

REMARKS***The Present Invention and the Pending Claims***

The advantage of the present invention is that the claimed methods provide the ability to detect the taxonomic unit of enterobacteria. The advantage of being able to detect the taxonomic unit of enterobacteria is, for example, in a quality analysis of materials, such as food. By carrying out only one analysis as claimed, one of ordinary skill in the art is able to tell whether the material is free of any kind of enterobacteria. One would not be required to test the material multiple times, each time for a specific species of enterobacteria. Therefore, the analysis of the material using the claimed methods provides a single-step analysis with information as to whether or not an enterobacterium is contaminating the material.

With entry of the amendment, claims 86, 88, 89, 92-94, 96, 97, 100, 102, 105, and 107 are pending.

The Office Action

The Office Action rejects claims 86-89, 96-98, 100, 102, 103, and 105 under 35 USC Section 103 (a) as allegedly unpatentable over Mariani et al. (U.S. Patent 5,654,141; herein the '141 patent) in view of Yamamoto et al. (GenBank Accession Number AB001341, submitted January 25, 1997). Reconsideration of this rejection is hereby requested.

Examiner Interview

Applicants wish to thank Examiner Calamita for the interview which took place on February 7, 2006. In the interview, the amendment of the claims to read on SEQ ID NOs: 2 and 78, instead of SEQ ID NOs: 2 and 25, was discussed. Examiner Calamita agreed to examine the amended claims directed to methods involving SEQ ID NOs: 2 and 78 upon the filing of a Request for Continued Examination.

The Amendments to the Claims

Claims 87, 90, 91, 95, 98, 99, 101, 103, 104, and 106 have been canceled. Applicants reserve the right to pursue any canceled subject matter in a continuation, continuation-in-part, or divisional application.

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Claim 86 has been amended to recite "a method for detecting the taxonomic unit of enterobacteria in an analytical sample" which is supported by the specification at, for instance, page 7, lines 29 through page 8, line 4. Claim 86 also has been amended to recite "at least one of the added nucleic acids." Further, claim 86 has been amended to delete "a nucleic acid according to a)" in part b) and "or b)" in part c). Claims 86 and 92 have been amended to recite "at least 70%" in part c) of each claim. Claims 88, 89, 93, and 94 have been amended to recite "method" in lieu of "process." Claims 88 and 93 have been amended to recite "bacterial nucleic acid."

Claim 92 has been amended to list the steps comprising the method. Also, "especially genera and species, using primers in which in" has been deleted, and the claim now recites "comprising a first amplification step in which the DNA for a taxonomic unit of the enterobacteria family is amplified with conserved primers to obtain a first amplification fragment." Also, "high" and "units such as classes, phyla or families" has been deleted from claim 92. Further, claim 92 has been amended to recite "which are specific for genera or species of the taxonomic unit" and "wherein the primers used in the first amplification step comprise a nucleic acid selected from the group consisting of."

Claim 94 has been amended to recite "claim" with a lower case "c." Claims 96 and 102 have been amended to delete "alternative" and "or b)." Claim 97 has been amended to recite "wherein the one or more nucleic acid molecules are...so that they can generate a signal for analytical detection, with the modification or labeling selected from the group consisting of..." Also, "especially using antibodies, antigens, enzymes, and/or substances with affinity to enzymes or enzyme substrates" has been deleted and this subject matter is now the subject matter of new claim 107.

Claim 100 has been amended to be an independent claim, since the claim on which claim 100 previously depended (i.e., claim 90) was canceled. Accordingly, the language of canceled claim 90 has been inserted into claim 100. Claim 100 has also been amended to recite "bacteria having a bacterial nucleic acid" and "hybrid nucleic acids comprising one or more of the contacted nucleic acids." Claims 100 and 102 have been amended by deleting "or b)." Claims 86, 92, 100, and 105 have further been amended to read on only SEQ ID NOS: 2 and 78. Claim 105 has been amended to be an independent claim, since the claim on which

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claim 105 previously depended (i.e., claim 95) was canceled. Accordingly, the language of canceled claim 95 has been inserted into claim 105. Furthermore, "a combination of" has been inserted into each of parts a) to d) of claim 105 and the language of each of these parts has been amended to be grammatically correct. Claim 105 has also been amended to recite "which are specific for genera or species of the taxonomic unit."

No new matter has been added by way of these amendments.

Discussion of the Obviousness Rejection

The Office Action rejects claims 86-89, 96-98, 100, 102, 103, and 105 under Section 103 (a) as allegedly unpatentable over the '141 patent in view of Yamamoto et al. The Office Action also relies upon Buck et al., *BioTechniques* 27:528-536 (1999), in support of the obviousness rejection.

Specifically, the Office Action alleges that the '141 patent discloses certain features of a method for detecting bacteria in an analyzed sample as claimed in claims 86-89, 91-94, and 97. The Office Action admits that the '141 patent does not teach the primer pair of SEQ ID NOS: 2 and 25. The Office Action further alleges that Yamamoto et al. discloses SEQ ID NOS: 2 and 25. The Office Action moreover relies on the teachings of Buck et al. to demonstrate that one of ordinary skill in the art would have a reasonable expectation of success with the primers allegedly disclosed by Yamamoto et al. for use in the method of detecting bacteria in an analytical sample, which method is purportedly disclosed by the '141 patent. This rejection is traversed for the reasons set forth below.

Claims 87, 98, and 103 have been canceled. Thus, the rejection as it pertains to these claims is moot.

The Office Action on page 3 states that Mariani et al. allegedly teaches a method of detecting enterobacteria in an analytical sample, since Mariani et al. allegedly teaches a species of enterobacteria, namely, *E. coli* (column 2, lines 52-54 and example 1). However, Mariani et al. does not teach a method of detecting *a taxonomic unit of enterobacteria*. On the contrary, Mariani et al. discloses a method of detecting *E. coli*, *Streptococci*, *Staphylococci*, and/or *Bacteroides* by using sequences, which target the 16S rRNA gene, which gene is conserved among these bacteria, or sequences which target the *ial* gene of *E. coli*, the enterotoxin A gene of

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Staphylococcus, or the non conserved region of the 16S gene of *Bacteroides fragilis*.. *Streptococci*, *Staphylococci*, and *Bacteroides*, however, are not enterobacteria. Thus, the method of Mariani et al. in which sequences, which target the 16S rRNA gene, are used would detect bacteria other than enterobacteria, and the method of Mariani et al. in which sequences, which target the ial gene of *E. coli*, are used would not necessarily detect other enterobacterial species, such as *Yersinia aldovae*. Therefore, Mariani et al. does not teach the presently claimed methods.

Also, the pending claims have been amended as discussed. None of the cited references, including Yamamoto et al., teaches or suggests SEQ ID NO: 78, let alone a *combination* of SEQ ID NOS: 2 and 78. Therefore, the '141 patent and Yamamoto et al. cannot support an obviousness rejection of claim 105.

Furthermore, as stated in the previously-filed Reply (mailed on September 16, 2005), the sequence of Yamamoto et al. is 16,446 basepairs in length, whereas SEQ ID NOS: 2 and 78 are 20 and 30 basepairs, respectively. Neither Yamamoto et al. nor the '141 patent, either alone or in combination, teach or suggest a particular region of the sequence of Yamamoto et al. which could be used in a method of detecting a bacteria, e.g., an entire taxonomic unit of enterobacteria, in an analytical sample, let alone teach that SEQ ID NO: 2 or SEQ ID NO: 78, in specific, can be used in such a method.

There is no pointer to the specific selection of SEQ ID NOS: 2 and 78. It has been held by the Federal Circuit that lack of motivation to select a particular DNA sequence, among all of the possible degenerate variants was a factor in *In re Duel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) ("There must, however, still be prior art that suggests the claimed compound in order for a *prima facie* case to be made out...") *In re Duel*, which the Office Action relies on, establishes that a claim drawn to a cDNA with a particular, defined nucleotide sequence is not *prima facie* obvious in view of a reference disclosing the protein sequence and a reference disclosing the cloning method, regardless of how routine the method might be. Here, there is no adequate teaching which of the myriad possible sequences would work as a primer.

The Office Action aligns SEQ ID NO: 2 with Yamamoto et al.'s sequence spanning 11799 to 11780. This is a classic case of hindsight reconstruction. There is absolutely no teaching to pick this region in Yamamoto et al. The Office Action has employed applicants'

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invention as a roadmap to make the *prima facie* case. It is well established that it is improper to "use that which the inventors taught against its teacher." *In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430 (Fed. Cir. 2002). Using an applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of § 103 which requires judging obviousness as the point in time when the invention was made. See *Grain Processing Corp. v. American Maize Products Co.*, 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).

In view of the foregoing, the obviousness rejection cannot stand. Applicants, therefore, respectfully request that the rejection be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Xavier Pillai, Reg. No. 39,799
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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